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ANA LYTICAL METHOD DEVELOPMENT AND VALIDATION OF DONEPEZIL HCL IN TABLET DOSAGE FORM BY UV SPECTROSCOPIC METHOD

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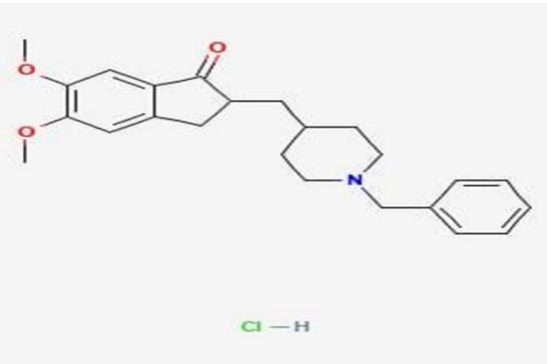
ABSTRACT

A new simple, accurate, rapid, precise, reproducible and cost-effective spectrophotometric method for the quantitative estimation of Donepezil Hcl in tablet dosage form. The developed UV spectrophotometric method for the quantitative estimation of Donepezil Hcl is based on measurement of absorption at maxima wavelength 316nm using Ethanol. The standard and sample solution were prepared by using Ethanol as a solvent. Quantitative determination of the drug was performed at wavelength range nm. The linearity was established over the concentration range 5, 10, 15, 20, 25, µg/ml for the Donepezi Hcl with correlation coefficient value of 1 Precision studies showed that 1% relative standard deviation was within range of acceptable limits. The mean percentage recovery was found to be 98.6%. The proposed method has been validated as per ICH guidelines.

KEYWORDS: Donepezil Hcl, UV spectrophotometer, Method development, Validation, Accuracy, Precision.

INTRODUCTION

DONEPEZIL HCL- 2-[(1-benzylpiperidin-4-yl)methyl]-5,6-dimethoxy- 2,3-dihydroinden-1-one;hydrochloride. Donepezil hydrochloride is a medication primarily used to treat Alzheimer's disease. It belongs to class of drugs known as acetyl cholinesterase inhibitors, designed to enhance cognitive function by increasing Acetylcholine levels in the brain. Donepezil inhibits Acetyl cholinesterase, an enzyme that breaks down Acetylcholine. By inhibiting this enzyme, Donepezil increases acetylcholine levels, improving communication between nerve cells and potentially mitigating cognitive decline.



STRUCTURE OF Donepezil

This drug is well absorbed through oral administration, distributed by crossing the blood brain barrier, metabolised in liver by CYP3A4 and CYP2D6 enzymes and Eliminated through urine. This drug comes under the category of cholinesterase inhibitors.

MATERIALS AND METHODS

Chemical and Reagents: - Ethanol (100%)

Instrument: SHIMADZ UV 1601UV -VIS Spectrophotometer, Electronic Balance (CITIZEN BALANCE BL-220H), Ultra Sonicator (ANALYTICAL), and PH meter (Elico-Li120), Pipettes and Burettes (Borosil), Beakers (Borosil).

Reagents and solutions

Diluent preparation: Ethanol (100%).

Preparation of Sample Solutions

Take 4 Tablets average weight and crush in a mortar by using pestle and weight powder 100 mg equivalent weight of Donepezil sample into a 100ml equivalent weight of Donepezil sample in to a sample in to a 100 ml clean dry volumetric flask, dissolve and make up to volume with diluent. Further dilution was done by transferring 0.1ml of the above solution in to a 10ml volumetric flask and make up to volume with diluent.

Determination of wavelength of maxima absorbance of Donepezil

The Determination of wavelength of maximum absorbance for Donepezil. The absorbance of the final solution scanned in the UV spectrum in the range of 200-400 against solvent mixture as blank.

Optimization of selection of Solvent

It is well known that the solvents do exerts a profound effect on the quality and the shape of the peak. The choices of solvents for UV method development are: Methanol, Ethanol, acetonitrile, benzene etc. First optimize the different solvents. From that solvents, Ethanol satisfied the all the optimized conditions.

Wavelength Selection

The standard solutions are preparing by transferring the standard drug in a selected solvent or mixture of solvent and finally diluting with the same solvent or diluent. That prepared solution is scanned in the UV wavelength range of 200-400nm.This has been performed to know the maxima of Donepezil. While scanning the Donepezil solution we observed the maxima at 316 nm. The UV spectrum has been recorded on (SHIMADZU UV-1601) make UV–Vis spectrophotometer model UV-1601.The scanned UV spectrum is attached in the following page. The λmax of the Donepezil was found to be 316nm in diluents as solvent system.

METHOD VALIDATION

Accuracy

Recovery study: To determine the accuracy of the proposed method, recovery studies were carried out by adding different amounts (75%, 100%, and 125%) of Donepezil Hcl tablet powder were taken and added to the pre-analysed formulation of concentration 10µg/ml. From that percentage recovery values were calculated. The results were shown in Table-1.

Precision

Repeatability: The Precision of each was method ascertained separately. From the peak areas & retention times obtained by actual determination of six replicates of a fixed amount of drug. Donepezil (tablet dosage form) the percent relative standard deviations were calculated of Donepezil revealed that the proposed method is precise. The results were shown in Table-2.

Linearity & Range

The calibration curve showed good linearity in the range of 5-25µg/ml, for Donepezil Hcl with correlation coefficient (R^2) of 1. A typical calibration curve has the regression equation of y = 0.034x+0.0038 for Donepezil Hcl.

Standard solutions of Donepezil in the concentration range of 5 µg/ml to 25 µg/ml were obtained by transferring (5,10,15,20 and 25 ml) of Donepezil Hcl stock solution (100ppm) to the series of clean & dry 10 ml volumetric flasks. The volumes in each volumetric flask were made up with the solvent system and mixed.

The absorbances of the solutions were measured at 316 nm against the solvent system as blank and calibration curve is plotted. The Lambert-Beer's Law is linear in concentration range of 5 to 25 µg/ml at 316nm for Donepezil Hcl. The results were shown in Table-4.

Method Robustness

Robustness of the method was determined by carrying out the analysis under different Wavelength i.e., at 314 nm, and 318 nm. The respective absorbances of 10µg/ml were noted SD < 2%) the developed UV-Spectroscopic method for the analysis of Donepezil (Tablet dosage form). The results were shown in Table-5.

LOD & LOQ

The LOD and LOQ were calculated by the use of the equations LOD = 3.3 × σ / S and LOQ = 10 × σ / S where σ is the standard deviation of intercept of Calibration plot and S is the average of the slope of the corresponding Calibration plot.

The Minimum concentration level at which the analyte can be reliable detected (LOD) & quantified (LOQ) were found to be 0.29865µg/ml and0.905µg/ml Respectively.

RESULTS AND DISCUSSION

The standard solutions of Donepezil Hcl with Ethanol(10µg/ml) subjected to a scan individually at the series of wavelength of 200-400nm. Absorption maxima of Donepezil Hcl was found to be at 316nm. Therefore, 316nm was selected ⅄max of Donepezil for the present study. The calibration curve of Donepezil can be determined without interference of ant irrelevant substance in single component pharmaceutical products. The used technique was initially attempted on bulk drugs in their synthetic sample and concentrations were estimated.

The % recovery was carried out at 3 levels, 75%, 100% and 125% of Donepezil Hcl standard concentration. Three samples were prepared for each recovery level. The solutions were then analyzed, and the percentage recoveries were found to be satisfactory within the acceptable limits as per the content of the label claim for marketed tablet dosage form. The newly developed method was validated according to the ICH guidelines and the method validation parameters.

The developed method was subjected to do the various method validation parameters such as accuracy, precision, linearity and range, limit of detection and limit of quantification, robustness and ruggedness etc.

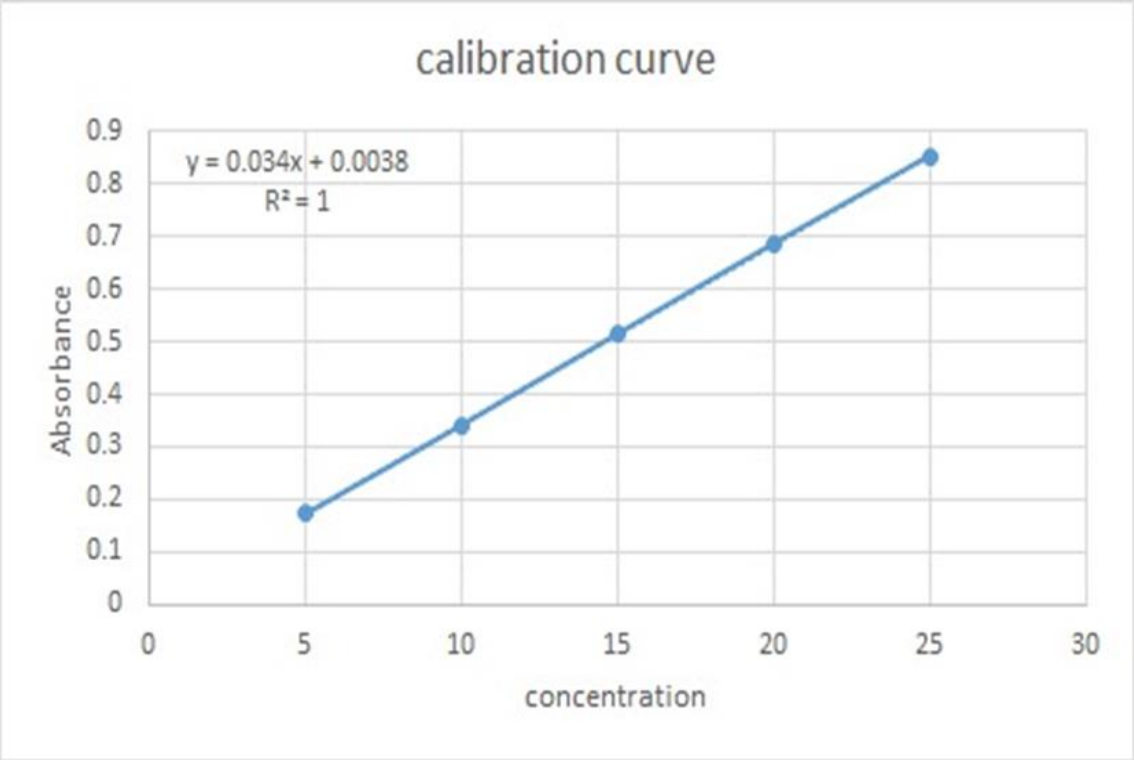


Fig 2: Calibration Curve of Donepezil Hcl.

Table 1: Results of Accuracy.

Level of Recovery	Sample conc.(µg/ml)	Absorbance	Amount Recovery (µg/ml)	%Recovery	Mean %Recovery
75%	7.5	0.1393	7.46	99.57	98.97
75%	7.5	0.1393	7.45	99.42	
75%	7.5	0.137	7.344	97.92	
100%	10	0.171	9.395	97.20	98.50
100%	10	0.174	9.56	99.44	
100%	10	0.177	9.725	99.88	
125%	12.5	0.213	11.626	97.37	98.39
125%	12.5	0.222	12.117	99.56	
125%	12.5	0.224	12.226	98.25	

Acceptance criteria: correlation coefficient should not less than 0.999
Repeatability

Table 2: Results of Repeatability.

S.NO	Conc(µg/ml)	Wavelength (nm)	Absorbance
1	10	316	0.171
2	10	316	0.169
3	10	316	0.172
4	10	316	0.172
5	10	316	0.168
6	10	316	0.169
Mean ± S.D.			0.170
Standard Deviation			0.003077
% RSD			1.817005

Table 3: Results of Linearity.

S.NO	Concentration (µg/ml)	ABSORBANCE
1	5	0.174
2	10	0.342
3	15	0.515
4	20	0.686
5	25	0.852

Acceptance criteria correlation coefficient should not be less than0.999.

Table 4: Result of Method Robustness.

Concentration(µg/ml)	Wavelength	Absorbance	Statistical Analysis
10	314	0.173	Mean=0.172333 SD=0.002338 %RSD=1.356726
10		0.169	
10		0.172	
10	318	0.173	
10		0.176	
10		0.171	

CONCLUSION

From the experimental studies it can be concluded that first UV-Spectroscopic method is developed for Donepezil Hcl in marketed pharmaceutical dosage form. The developed method for the drug (Donepezil Hcl) was found to be accurate and precise.

The great features of spectrophotometric methods are their simplicity, economical and rapidity. In this method Ethanol is used as diluent. The results of method validation showing that the developed analytical procedure is suitable for its intended purpose and meets the Guidelines given by the ICH.

The result shows the developed method is yet another suitable method for assay, purity which can help in the analysis of Donepezil Hcl in Tablet formulations.

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